REMARKS

This Amendment and Response amends claims 5. With this Amendment and Response, claims 5-7 are pending in this application.

I. Amendments to the Specification and the Drawings

Applicants submit that the amendments to the specification and the deletion of Figure 8 are being made in order to remove matter which is presently claimed in Application Serial No. 10/306,062. The removal of this matter is done without prejudice or disclaimer to the subject matter thereof.

II. Claim Objections

The Action objects to claims 5-7 as being dependent on non-elected claims. Applicant has amended claim 5 to include the subject matter of claim 1, the non-elected claim to which it originally depended. Application submits that the Action's objections to claims 5-7 have thus been overcome.

III. 35 U.S.C. §112 Rejections

The Action rejects claims 5-7 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejections are apparently based on the Action's rejection of claim 5 as vague and indefinite by the use of the phrase, "induce immunity in a patient."

The Action states that it is unclear what is meant by that phrase. Applicant submits that the phrase, by its plain and ordinary meaning, means to induce an immunological

response in a patient. Support for this meaning is found throughout the application, particularly p. 18, paragraphs 2 and 3. Applicant submits that the use of the phrase "induce immunity in a patient" does not render claim 5 vague and indefinite, particularly when the claim is read in light of the specification. Thus, Applicant respectfully requests that the rejection be withdrawn.

IV. 35 U.S.C. §102 Rejections

The Action rejects claims 5-7 under 35 U.S.C. §102(b) as being anticipated by Relyveld (U.S. Patent 4,016,252). Applicant respectfully traverses this rejection and request reconsideration and withdrawal thereof.

The Action has characterized Relyveld as disclosing an aqueous gel of calcium phosphate useful for preparation of adsorbed vaccines, prepared by contacting an antigen with the aqueous gel, and their use as vaccines (i.e. induce immunity). The Action states that Relyveld discloses the claimed particle sizes, because the gel "exhibits a marked colloidal character" and "it is well known in the art that colloid is defined as a substance consisting of very tiny particles that are usually between 1 nm and 1000 nm in diameter and that are suspended in a continuous medium, such as a liquid, a solid or a gaseous substance."

Claim 5 has been amended to include the limitation that the particle "has a substantially spherical shape and a substantially smooth surface." Relyveld does not disclose such a particle. Moreover, the fact that the Relyveld particles have a certain composition and size or that they are "colloidal" does not anticipate "substantially smooth" particles. There is no disclosure in Relyveld of the particles having a particular morphology, other than the statement that the gel exhibits "colloidal character."

The Examiner cites a definition of "colloid" meaning "a substance consisting of very tiny particles that are usually between 1 nm and 100 nm in diameter and that are suspended in a continuous medium. . . ." In other words, the particles are not readily filtered out from the gel. The term "colloid" does not mean or infer a "substantially smooth" particle. The "substantially smooth" particles of the present invention are newly attainable through the additional control over the size and shape of the particles which is characterized by the process of the present invention. The degree of control over the size and shape of the particles of the present invention, and ability to attain "substantially smooth" and "substantially spherical" particles, results in greater control over the degree of antigenic material saturation which can be achieved in the particle.

Relyveld also states that the "particles of special calcium phosphate of the present invention are considerably finer than those hitherto known and used calcium phosphate gels." The particles of the suspension should be as fine as possible, which requirement is well met by the gel because it "exhibits a marked colloidal character." In other words, Relyveld attributes the colloid character of its gel to the fact that the velocity of settling of the gel is slower than that of conventional calcium phosphate gel. Relyveld uses the term "colloidal character" to mean that its particles are so find that they remain suspended in a continuous medium, not to refer to their morphology.

Although Relyveld's particles are "considerably finer than those hitherto known," (when the Relyveld specification was written), the particles of the present invention may be an even smaller size. Relyveld's rapid formation would change the size of the particles and cause them to be larger than the particles of the presently claimed invention. Relyveld

emphasizes, and recites in its claims, specific ratios of calcium to phosphate. The high molar concentration of its reactants will cause the gel of Relyveld to be highly amorphous, also resulting in particles that are larger than those of the presently claimed invention. Having provided no basis or technical reasoning to support the assertion that the "substantially smooth" and "substantially spherical" features of the present invention necessarily flow from the Relyveld disclosure, Applicants respectfully assert that the rejections based on §102(b) are improper and asks that they be withdrawn.

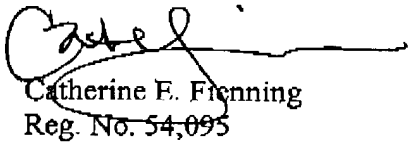
MPEP §2131 requires that to anticipate a claim, the reference must teach *every element* of the claim. (emphasis added). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. V. Union Oil Co. of Calif.*, 814 F.3d 628, 631 (Fed. Cir. 1987). The claims of the present application are directed to methods of inducing immunity in a patient through the delivery compositions of calcium phosphate in which an antigenic material partially coats or is impregnated within the particles. Relyveld does not contain the limitations that the antigenic material may coat the particle, may be impregnated in the particle, or both. In fact, the process of preparing the Relyveld particles negates the ability of those particles to incorporate the antigenic materials as described in the present invention. Relyveld does not provide that the antigenic material may be impregnated within the calcium phosphate particles. Additionally, the washing and purification steps described in the Relyveld disclosure would result in the destruction of the antigenic materials coated on the particles as described in the present invention.

The present invention also contains the additional limitation that the calcium phosphate particles are adapted to produce an immune response in a patient in need thereof. Relyveld does not disclose this characteristic. Although Relyveld discloses a calcium phosphate gel for use in adsorbing vaccines, nowhere does it disclose that the gel is adapted to produce an immune response in a patient. In contrast, the Relyveld particles adsorb vaccines, meaning they "attract and hold molecules of another substance to the surface of its molecules." *See* On-Line Medical Dictionary at http://www.graylab.ac.uk/cgi-bin/omd?adsorb. To adsorb a vaccine, the antigenic material must be adhered to the particles. Adsorption of the vaccine teaches away from the present invention which allows the antigenic materials to be readily released into the system, thus producing the immune response called for in the claims. For at least these reasons the Examiner's rejections to claims 5-7 should be withdrawn. Relyveld does not anticipate Claim 5, nor claims 6-7 which depend from it, and these rejections should be withdrawn.

CONCLUSION

Applicants respectfully submit that claims 5-7 are in condition for immediate allowance, and request early notification to that effect. If any issues remain to be resolved, the Examiner is respectfully requested to contact the undersigned at 404.532.6938 to arrange for a telephone interview prior to issuance of a Final Office Action.

Respectfully submitted,



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